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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,578	02/28/2002	David A. Watson	WATSON-39632	3902
26252	7590	06/23/2004	EXAMINER	
KELLY BAUERSFELD LOWRY & KELLEY, LLP 6320 CANOGA AVENUE SUITE 1650 WOODLAND HILLS, CA 91367			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3762	3

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,578

Applicant(s)

WATSON, DAVID A.

Examiner

Leslie R. Deak

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 23-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-22, drawn to an indwelling shunting catheter, classified in class 604, subclass 8.
 - II. Claims 23-40, drawn to a method of making an indwelling catheter with phase inversion processes to apply a treating drug, classified in class 424, subclass 417.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions in Group I and Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the invention as claimed does not need the phase inversion coating process as claimed in the method of making, as the catheter can be coated with treating material in any conventional manner.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Scott Kelley on 14 June 2004, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-22. Affirmation of this election must be made by applicant in replying to this Office action.

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Claims 23-40 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-8 and 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,601,724 to Hooven et al in view of US 4,767,400 to Miller et al. Hooven discloses an indwelling catheter with a length of flexible tubing and a porous segment that is reinforced by the underlying tubular member and comprises a series of micro-orifices, which may be about 5 microns in size (see columns 3-5, FIGS 3-7). "About" 5 microns includes 4.99 microns, and Hooven discloses that the micro orifices should be small enough to prevent tissue growth therein. Hooven further discloses a rounded, tapered distal nonporous tip on the catheter. Hooven fails to disclose that the perforated portion comprises a polymeric fiber membrane, but Miller discloses an indwelling catheter with a wound fiber membrane at the distal end wherein the fibers are wound tightly to create a permeable membrane with micro openings to allow CSF to flow freely therethrough, increasing the porosity of the distal end (see columns 2, 5-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to make the reinforced porous distal end of the catheter disclosed by Hooven out of a fiber

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membrane in order to increase the porosity of the distal end of the catheter, as taught by Miller.

With regard to applicant's claim drawn to the method of making the claimed catheter via a phase inversion process, the method of forming the device is not germane to the issue of the patentability of the device itself. Therefore, this limitation has not been given patentable weight.

With regard to applicant's claim drawn to the composition of the fiber membrane, both Hooven and Miller indicate that the porous portion of the catheter is made of any suitable polymer. It would have been obvious to one of ordinary skill in the art at the time of invention to make the porous portion of the catheter out of polyether sulfone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis for the intended use as a matter of obvious design choice. See MPEP 2144.07.

With regard to the flow rate of the porous portion of the catheter, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. Furthermore, It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the same claimed structural limitations. See MPEP 2114. As such, the Hooven and Miller catheters are capable of having a the instantly claimed flow capacity, since the pore sizes in both devices are variable.

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With regard to applicant's claim limitation drawn to the size of the pores, Miller discloses that the pores should be sufficiently small to allow passage of CSF and prevent ingrowth of tissue. It would have been obvious to one of ordinary skill in the art at the time of invention to make the pore sizes smaller, since the mere change in size of a component involves only routine skill in the art. See MPEP 2144.04.

7. Claims 9-11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,601,724 to Hooven et al in view of US 4,767,400 to Miller et al, further in view of EP 0 823 262 A2 to Samson. Hooven and Miller fail to disclose a braided or coiled polymer or metal as the reinforcing member in the disclosed catheter. Samson discloses a catheter with braided and coiled reinforcing members made of polymeric ribbons and metal in order to make the catheter strong and kink resistant while retaining flexibility (see pages 6, 7). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to reinforce the catheter with micro openings disclosed by Hooven and Miller with woven, braided, or coiled polymer or metal strands, as taught by Samson, in order to provide strength and retain flexibility in the catheter.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 5,569,219 Hakki et al
 - i. Catheter with coiled reinforcing spring.

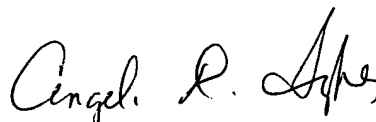
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd
15 June 2004



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